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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,839	05/18/2006	Derek Nigel John Hart	DAVI257.002APC	8032
20995	7590	12/17/2008		
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 12/17/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,839	<b>Applicant(s)</b> HART ET AL.	
	<b>Examiner</b> ANNE M. GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 57-65 is/are pending in the application.
- 4a) Of the above claim(s) 62-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claim 57 has been amended.

Claims 62-65 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 6, 2008.

2. Claims 57-61 are under examination.
3. The following Office Action contains NEW GROUNDS of Rejection.

### ***Objections Withdrawn***

4. The objections to the specification are withdrawn in view of applicant's amendments to the specification.

### ***Rejections Withdrawn***

5. The rejection of claims 57-61 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting a nucleotide sequence having identity to an amino acid sequence is withdrawn in view of applicant's amendment to the claims.
6. The rejection of claims 57-61 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's arguments.

***Rejections Maintained/ NEW GROUNDS of Rejection***

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 57-61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed September 8, 2008 has been carefully considered but is deemed not to be persuasive. The response states that those of skill in the art could readily envision all of the amino acid sequences that are 95% identical to the amino acid encoded by SEQ ID NO: 4. Those skilled in the art could recognize amino acid sequences that are 95% identical to the amino acid encoded by SEQ ID NO: 4 by comparing a given sequence to the amino acid sequence encoded by SEQ ID NO: 4. The level of skill and knowledge in the art is such that one of ordinary skill would be able to make and identify amino acid sequence variants having 95% identity to the amino acid encoded by SEQ ID NO: 4 routinely (see response pages 6-7).

In response to this argument, the standard for written description is what the applicant was in possession of at the time the instant application was filed, not what one of skill in the art could make and/or use. The instant specification discloses an antibody that binds to SEQ ID No. 4. Applicant points to pages 17 and 51 to provide support for an amino acid sequence having 95% identity to SEQ ID No. 4 (see response page 7).

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While these pages provide support for an amino acid sequence having 95% identity to SEQ ID No. 4 and generally for the production of antibodies, there is no evidence provided that applicant was in possession of an antibody that would bind to amino acid sequences having 95-99% identity to SEQ ID No. 4.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

9. Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed September 8, 2008 has introduced NEW MATTER into the claims. Newly amended claim 57 recites "or a protein encoded by a nucleotide sequence that hybridizes to the polynucleotide of SEQ ID No. 4 under high stringency conditions." The response pointed to pages 17 and 19 of the specification for support for newly amended claim 57 in the originally filed disclosure. These portions of the specification generally discuss percent identity of proteins and stringent conditions for hybridization respectively. The specification does not disclose an amino acid sequence encoded by the nucleotide which hybridizes to the sequence of SEQ ID No. 4. Instant claim 57 now recites limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations

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recited in claim 57, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claim 57 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

### ***Conclusion***

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 11, 2008

/David J Blanchard/  
Primary Examiner, Art Unit 1643